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November 8, 2002

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Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Utility Patent Application
Appl. No. 10/070,664 (which is the U.S. Natl. Stage of PCT Appl. No. PCT/CA00/01052)
I.A. Filing Date: September 8, 2000
For: **Diagnosis, Prognosis and Treatment of Trinucleotide Repeat-Associated Diseases and Intranuclear Inclusions-Associated Diseases**
Inventors: Rouleau *et al.*
Our Ref: 1619.0110000/SRL/AGU

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;

2. Form PTO-1449, 15 pages, listing 43 documents;

3. One copy of each of the 43 cited documents on Form PTO-1449; and

4. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Angelique G. Uy
Agent for Applicants
Registration No. 48,832

SRL/AGU/jk
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 9379
ROULEAU *et al.*	Art Unit: *To be assigned*
Appl. No. 10/070,664 (US Natl. Phase of PCT/CA00/01052)	Examiner: *To be assigned*
I.A. Filing Date: September 8, 2000	Atty. Docket: 1619.0110000/SRL/AGU
For: **Diagnosis, Prognosis and Treatment of Trinucleotide Repeat-Associated Diseases and Intranuclear Inclusions-Associated Diseases**	

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First Supplemental Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on July 11, 2002 in connection with the above-captioned application. A copy of each document is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: 11/08/02

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FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1619.0110000/SRL/AGU	APPLICATION NO. 10/070,664 (US Natl. Phase of PCT/CA00/01052)
	APPLICANT Rouleau *et al.*	
	INTL. FILING DATE September 8, 2000	GROUP *To be assigned*

U.S. PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	3	Akarsu, A.N., *et al.*, "Genomic structure of *HOXD13* gene: a nine polyalanine duplication causes synpolydactyly in two unrelated families," *Hum. Mol. Gen.* 5:945-952, Oxford University Press (1996)
	AT	3	Blondelle, S.E., *et al.*, "Polyalanine-Based Peptides as Models for Self-Associated β-Pleated-Sheet Complexes," *Biochemistry 36*:8393-8400, American Chemical Society (1997)

EXAMINER	DATE CONSIDERED

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Chung, M-y., *et al.*, "Evidence for a mechanism predisposing to intergenerational CAG repeat instability in spinocerebellar ataxia type I," *Nat. Gen.* 5:254-258, Nature Publishing Co. (1993)
	AS	4	Cooper, J.K., *et al.*, "Truncated N-terminal fragments of huntingtin with expanded glutamine repeats form nuclear and cytoplasmic aggregates in cell culture," *Hum. Mol. Gen.* 7:805-812, Oxford University Press (May 1998)
	AT	4	Cummings, C.J., *et al.*, "Chaperone suppression of aggregation and altered subcellular proteasome localization imply protein misfolding in SCA1," *Nat. Gen.* *19*:148-154, Nature Publishing Co. (June 1998)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	David, G., *et al.*, "Cloning of the *SCA7* gene reveals a highly unstable CAG repeat expansion," *Nat. Gen.* 17:65-70, Nature Publishing Co. (1997)
	AS	5	DiFiglia, M., *et al.*, "Aggregation of Huntingtin in Neuronal Intranuclear Inclusions and Dystrophic Neurites in Brain," *Science* 277:1990-1993, American Association for the Advancement of Science (1997)
	AT	5	Farabaugh, P.J., "Programmed Translational Frameshifting," *Annu. Rev. Genet.* 30:507-528, Annual Reviews, Inc. (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Forood, B., *et al.*, "Formation of an Extremely Stable Polyalanine β-Sheet Macromolecule," *Biochem. Biophys. Res. Commun. 211*:7-13, Academic Press, Inc. (1995)
	AS	6	Hardy, J., and Gwinn-Hardy, K., "Genetic Classification of Primary Neurodegenerative Disease," *Science 282*:1075-1079, American Association for the Advancement of Science (November 1998)
	AT	6	Holmberg, M., *et al.*, "Spinocerebellar ataxia type 7 (SCA7): a neurodegenerative disorder with neuronal intranuclear inclusions," *Hum. Mol. Gen.* 7:913-918, Oxford University Press (May 1998)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Igarashi, S., *et al.*, "Suppression of aggregate formation and apoptosis by transglutaminase inhibitors in cells expressing truncated DRPLA protein with an expanded polyglutamine stretch," *Nat. Gen. 18*:111-117, Nature Publishing Co. (February 1998)
	AS	7	Ikeda, H., *et al.*, "Expanded polyglutamine in the Machado-Joseph disease protein induces cell death *in vitro* and *in vivo*," *Nat. Gen. 13*:196-202, Nature Publishing Co. (1996)
	AT	7	Imbert, G., *et al.*, "Cloning of the gene for spinocerebellar ataxia 2 reveals a locus with high sensitivity to expanded CAG/glutamine repeats," *Nat. Gen. 14*:285-291, Nature Publishing Co. (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Jackson, M., *et al.*, "The cortical neuritic pathology of Huntington's disease," *Neuropathol. Appl. Neurobiol. 21*:18-26, Blackwell Scientific Publications (1995)
	AS	8	Johnston, J.A., *et al.*, "Aggresomes: A Cellular Response to Misfolded Proteins," *J. Cell Biol. 143*:1883-1898, The Rockefeller University Press (December 1998)
	AT	8	Kurland, C., and Gallant, J., "Errors of heterologous protein expression," *Curr. Opin. Biotechnol.* 7:489-493, Current Biology Ltd. (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Linton, M.F., *et al.*, "Reading-frame Restoration by Transcriptional Slippage at Long Stretches of Adenine Residues in Mammalian Cells," *J. Biol. Chem.* 272:14127-14132, The American Society for Biochemistry and Molecular Biology, Inc. (1997)
	AS	9	Llinás, R., *et al.*, "Distribution and functional significance of the P-type, voltage-dependent Ca^{2+} channels in the mammalian central nervous system," *Trends Neurosci.* 15:351-355, Elsevier Science Publishers Ltd. (1992)
	AT	9	Lunkes, A., and Mandel, J.-L., "A cellular model that recapitulates major pathogenic steps of Huntington's disease," *Hum. Mol. Gen.* 7:1355-1361, Oxford University Press (September 1998)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Merry, D.E., *et al.*, "Cleavage, aggregation and toxicity of the expanded androgen receptor in spinal and bulbar muscular atrophy," *Hum. Mol. Gen.* 7:693-701, Oxford University Press (April 1998)
	AS	10	Mundlos, S., *et al.*, "Mutations Involving the Transcription Factor CBFA1 Cause Cleidocranial Dysplasia," *Cell 89*:773-779, Cell Press (1997)
	AT	10	Muragaki, Y., *et al.*, "Altered Growth and Branching Patterns in Synpolydactyly Caused by Mutations in HOXD13," *Science 272*:548-551, American Association for the Advancement of Science (1996)

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	AR	11	Nemeth, A., *et al.*, "Isolation of genomic and cDNA clones encoding bovine poly(A) binding protein II," *Nucleic Acids Res. 23*:4034-4041, Oxford University Press (1995)
	AS	11	O'Donovan, M.C., *et al.*, "Involvement of expanded trinucleotide repeats in common diseases," *The Lancet 348*:1739-1740, Lancet Press (1996)
	AT	11	Orr, H.T., *et al.*, "Expansion of an unstable trinucleotide CAG repeat in spinocerebellar ataxia type 1," *Nat. Gen. 4*:221-226, Nature Publishing Co. (1993)

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	AR	12	Paulson, H.L., *et al.*, "Machado-Joseph Disease Gene Product Is a Cytoplasmic Protein Widely Expressed in Brain," *Ann. Neurol.* *41*:453-462, Wiley-Liss (1997)
	AS	12	Paulson, H.L., *et al.*, "Intranuclear Inclusions of Expanded Polyglutamine Protein in Spinocerebellar Ataxia Type 3," *Neuron* *19*:333-344, Cell Press (1997)
	AT	12	Paulson, H.L., and Fischbeck, K.H., "Trinucleotide Repeats in Neurogenetic Disorders," *Ann. Rev. Neurosci.* *19*:79-107, Annual Reviews, Inc. (1996)

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	AR	13	Perez, M.K., *et al.*, "Recruitment and the Role of Nuclear Localization in Polyglutamine-mediated Aggregation," *J. Cell Biol. 143*:1457-1470, The Rockefeller University Press (December 1998)
	AS	13	Roizin, L., *et al.*, "Neuronal Nuclear-Cytoplasmic Changes in Huntington's Chorea: Electron Microscope Investigations," *Adv. Neurol. 23*:95-122, Raven Press (1979)
	AT	13	Rubinsztein, D.C., *et al.*, "Sequence variation and size ranges of CAG repeats in the Machado-Joseph disease, spinocerebellar ataxia type 1 and androgen receptor genes," *Hum. Mol. Gen. 4*:1585-1590, Oxford University Press (1995)

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FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1619.0110000/SRL/AGU	APPLICATION NO. 10/070,664 (US Natl. Phase of PCT/CA00/01052)
	APPLICANT Rouleau *et al.*	
	INTL. FILING DATE September 8, 2000	GROUP *To be assigned*

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	AL						Yes No
	AM						Yes No
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	AO						Yes No
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	AR	14	Sanpei, K., *et al.*, "Identification of the spinocerebellar ataxia type 2 gene using a direct identification of repeat expansion and cloning technique, DIRECT," *Nat. Gen. 14*:277-284, Nature Publishing Co. (1996)
	AS	14	Servadio, A., *et al.*, "Expression analysis of the ataxin-1 protein in tissues from normal and spinocerebellar ataxia type 1 individuals," *Nat. Gen. 10*:94-98, Nature Publishing Co. (1995)
	AT	14	Sharp, A.H., *et al.*, "Widespread Expression of Huntington's Disease Gene (IT15) Protein Product," *Neuron 14*:1065-1074, Cell Press (1995)

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	AR	15	Simmons, A.H., *et al.*, "Molecular Orientation and Two-Component Nature of the Crystalline Fraction of Spider Dragline Silk," *Science 271*:84-87, American Association for the Advancement of Science (1996)
	AS	15	Skinner, P.J., *et al.*, "Ataxin-1 with an expanded glutamine tract alters nuclear matrix-associated structures," *Nature 391*:971-974, erratum, p. 307, Macmillan Publishers Ltd. (January 1998)
	AT	15	Tomé, F.M.S., and Fardeau, M., "Nuclear Inclusions in Oculopharyngeal Dystrophy," *Acta Neuropathol. (Berl.) 49*:85-87, Springer-Verlag (1980)

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	AR	16	Trottier, Y., *et al.*, "Polyglutamine expansion as a pathological epitope in Huntington's disease and four dominant cerebellar ataxias" *Nature* 378:403-406 (1995)
	AS	16	van Leeuwen, F.W., *et al.*, "Frameshift Mutants of β Amyloid Precursor Protein and Ubiquitin-B in Alzheimer's and Down Patients," *Science* 279:242-247, American Association for the Advancement of Science (January 1998)
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	AR	17	Wells, R.D., "Molecular Basis of Genetic Instability of Triplet Repeats," *J. Biol. Chem. 271*:2875-2878, The American Society for Biochemistry and Molecular Biology, Inc. (1996)
	AS	17	Yvert, G., and Mandel, J.-L., "Variation on a trinucleotide theme," *Nat. Med.* 5:383-384, Nature American Inc. (April 1999)
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